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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,376	05/30/2001	Jeffrey P. Bodner	279.368US1	7232

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EXAMINER	
OROPEZA, FRANCES P	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,376	BODNER, JEFFREY P.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/13/04 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/8/04, 9/7/04, 12/13/04 JRO
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. Claims 24, 26, 28 and 29 stand rejected under 35 U.S.C. 102(b) as being anticipated by Comte (US 4640983). Comte teaches a conductor device connecting a cardiac electrode and an electrical pulse generator. The conductor device comprises multi-filar conductors (75, 85) wound coaxially and non-co-radially, the conductors are individually insulated or not, the conductor coils are separated by a sheathing/ tube of material (87), and the conductor are covered with an outer sheathing (77) (abstract; figure 8; col. 3 @ 59 – col. 4 @ 1; col. 9 @ 52–68; col. 10 @ 48-56; col. 10 @ 65 – col. 11 @ 6).

The Applicant's arguments filed 12/13/04 have been fully considered but they are not convincing.

The Applicant argues the sheathing disclosed by Comte is not an insulative coating, hence the reference does not disclose the Applicant's limitation of "providing a second conductor ... having a second outer filar diameter surrounded by an insulative coating". The Examiner disagrees. Comte teaches covering the conductor diameter with a sheathing made of elastomer (col. 10 @ 48-56). Elastomers are materials known to be insulative coatings (Comte – col. 3 @ 66-68).

Claim Rejections - 35 USC § 103

2. Claim 1-9, 11-14, 18-20, 22, and 25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Helland et al. (US 5545201). As discussed in

paragraph 1 of this action, Comte discloses the claimed invention except for an extendable/ retractable electrode (claims 1, 11, 18, 25) and a means of facilitating rotation of the second conductor (claims 8, 14).

Helland et al. teach an electrode configuration using an electrode assembly with an extendable/ retractable electrode (144) coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug (176) for the purpose of fixing/ securing the electrode to the heart wall. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an extendable/ retractable electrode coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug in the Conte system in order to accurately sense and stimulate the heart so there is accurate discrimination of the cardiac rhythm enabling effective therapy to be offered to the patient (figure 6; col. 1 @ 6-11 and 48-58; col. 1 @ 62 – col. 2 @ 5; col. 4 @ 56 – col. 5 @ 15).

The Applicant's arguments filed 12/13/04 have been fully considered but they are not convincing.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, combining Helland et al. with Comte, is supported by the Comte reference which

notes the conductor device of Comte can be used as part of a stimulation and/or measurement device (col. 1 @ 18-21) and the Helland et al. reference that teach use of passive fixation in the form of a screw mechanism and electrode spacing with a conductive device to enhance the electrical signal sensing capability (col. 1 @ 5-58), hence supporting the motivation to combine in the rejection of record and enabling the modified Comte device "to accurately sense and stimulate the heart so there is accurate discrimination of the cardiac rhythm enabling effective therapy to be offered to the patient".

3. Claims 10 and 15-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Helland et al. (US 5545201) and further in view of Doan (US 5425755) and further in view of Altman et al. (US 5845396).

As discussed in paragraphs 1 and 2 of this action, modified Comte discloses the claimed invention except the insulative coating being ETFE.

Doan teaches the lead insulation using a biocompatible TEFLON ™ coating, such as ETFE, for the purpose of minimizing the frictional resistance between the coated coil and the surrounding insulation. ETFE is a material well known in the conductor art for use as a conductor insulator (US 5845396 to Altman et al. – col. 7 @ 11-16). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an insulative coating of ETFE in the modified Conte system in order to reduce the coefficient of friction between the outer coil and outer insulation so the lead has increased flexibility facilitating the positioning and fixation in the heart, and so the torque associated with the inner coil and tubing is

reduced when the helix electrode is extended or retracted to minimize damage to the lead (abstract; col. 2 @ 17-26; col. 4 @ 5-10).

The Applicant's arguments filed 12/13/04 have been fully considered but they are not convincing.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, combining Doan with modified Comte, is supported by the Comte reference which notes the conductor device of Comte can be completely implanted in the body (col. 1 @ 18-21) and the Doan reference that teaches Teflon ™ reduces the friction between surfaces to enable lead insertion and helix movement (col. 3 @ 59 – col. 4 @ 14; col. 2 @ 39-52), hence supporting the motivation to combine in the rejection of record and enabling the modified Comte device "to reduce the coefficient of friction between the outer coil and outer insulation so the lead has increased flexibility facilitating the positioning and fixation in the heart, and so the torque associated with the inner coil and tubing is reduced when the helix electrode is extended or retracted to minimize damage to the lead".

4. Claim 21 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Helland et al. (US 5545201) and further in view of Altman et al. (US5845396). As discussed in paragraphs 1 and 2 of this action, modified Comte disclose the claimed invention except for the insulation being a polyimide material (claim 21), and the insulation being heat-shrunken PTFE / ETFE material (claims 23).

As to claim 21, Altman et al. teach signal conduction using a lead with polyimide coated conductors for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered (col. 1 @ 6-10; col. 2 @ 34-36).

As to claims 23, Altman et al. teach a lead with heat-shrunken PTFE / ETFE insulated conductors for the purpose of reinforcing the lead to resist the residual stresses in the coating. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunken PTFE/ ETFE insulated conductors in the modified Comte et al. system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads (col. 2 @ 59-64; col. 3 @ 26-42; col. 4 @ 25-32; col. 7 @ 11-16).

The Applicant's arguments filed 12/13/04 have been fully considered but they are not convincing.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case with regards to the polyimide material, combining Altman et al. with modified Comte is supported by the modified Comte reference which teaches the insulation on the conductor is a Teflon ™ (paragraph 3 of this Office Action) and the Altman et al. reference that teaches the coating is a fluoropolymer (Teflon ™) or polyimide (col. 2 @ 34-36), indicating the two coatings are functional equivalents and supporting the motivation to combine in the rejection of record: "It would have been an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered" (col. 2 @ 24-26).

In this case with regards to the heat-shrunken PTFE / ETFE material, combining Altman et al. with modified Comte is supported by the modified Comte reference which teaches the insulation on the conductor is a Teflon ™ (paragraph 3 of this Office Action) and the Altman et al. reference that teaches the coating can be the combined processes of heat-shrinking (thermal relaxation) with the wrapping of fluoropolymer (Teflon ™) tape to reduce residual stress in the coating on the cable, hence enabling producing of leads with more conductors and with smaller diameter conductors (col. 2 @ 59-64; col.3 @ 26-35 and 43-51; col. 4 @ 25-32), supporting the

motivation to combine in the rejection of record: "It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunken PTFE/ ETFE insulated conductors in the modified Comte et al. system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads".

5. Claim 27 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Altman et al. (US5845396). As discussed in paragraphs 2 of this action, Comte disclose the claimed invention except for the insulation being heat-shrunken PTFE / ETFE material.

Altman et al. teach a lead with heat-shrunken PTFE / ETFE insulated conductors for the purpose of reinforcing the lead to resist the residual stresses in the coating. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunken PTFE/ ETFE insulated conductors in the Comte system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads (col. 2 @ 59-64; col. 3 @ 26-42; col. 4 @ 25-32; col. 7 @ 11-16).

The Applicant's arguments filed 12/13/04 have been fully considered but they are not convincing.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case with regards to the heat-shrunken PTFE / ETFE material, combining Altman et al. with modified Comte is supported by the modified Comte reference which teaches the insulation on the conductor is a Teflon ™ (paragraph 3 of this Office Action) and the Altman et al. reference that teaches the coating can be the combined processes of heat-shrinking (thermal relaxation) with the wrapping of fluoropolymer (Teflon ™) tape to reduce residual stress in the coating on the cable, hence enabling producing of leads with more conductors and with smaller diameter conductors (col. 2 @ 59-64; col.3 @ 26-35 and 43-51; col. 4 @ 25-32), supporting the motivation to combine in the rejection of record: "It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunken PTFE/ ETFE insulated conductors in the modified Comte et al. system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads".

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (571) 272-4953. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

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2/9/05
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